DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 2, 2015

Shenzhen Mindray Bio-medical Electronics Co., Ltd
Yanhong Bai
Manager Regulatory Affairs
Mindray Building, Keji 12th Rd South, Hi-tech Industrial Park
Nanshan, Shenzhen 518057, P.R. China

Re: K150082
Trade/Device Name: Panorama Patient Monitoring Network
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, DSI, MLD, DRT, DQA, DRG, MSX
Dated: July 31, 2015
Received: August 5, 2015

Dear Yanhong Bai,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K150082

Device Name
Panorama Patient Monitoring Network

Indications for Use *(Describe)*

The indications for use for the Panorama Patient Monitoring Network include:
• Viewing real time patient clinical and demographic data
• Graphical and numeric trending of clinical data
• Storing and printing of clinical and demographic data
• Setting independent alarm limits for data sent by the bedside monitor

The clinical data displayed by the Panorama Patient Monitoring Network is obtained from one or more compatible physiological monitors and includes: ECG (Lethal and Non-Lethal Arrhythmia Detection, ST Segment Analysis, QT Analysis and heart rate(HR)), Invasive Blood Pressure (IBP), Non-Invasive Blood Pressure(NIBP), Blood Oxygenation (SpO2), Pulse Rate (PR), Respiration Rate (RESP), Respiration Gases(O2,CO2), Temperature(TEMP), Anesthetic Gases (AG), Cardiac Output(C.O.), Bispectral Index (BIS), and Hemodynamics.

The Panorama Patient Monitoring Network is intended for use in a fixed location, in the healthcare facility setting, as a central viewing station. The Panorama Patient Monitoring Network is not intended to be directly connected to the patient at any time or installed in a patient's vicinity.

The Panorama Network includes the Panorama Telemetry System which acquires and monitors physiological data for ambulating patients within a defined coverage area. The system processes the physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations. The Panorama Telemetry System is intended for installation in a hospital or clinical environment to provide clinicians with patient physiological data, while allowing for patient mobility.

The physiological parameters monitored through telemetry include ECG (Lethal and Non-Lethal Arrhythmia Detection, ST Segment Analysis, QT Analysis and heart rate(HR)), blood oxygenation (SpO2), Pulse Rate (PR). Received data is calculated at the Panorama Central Station, and can be displayed, trended, stored and printed at the Panorama Central Station.

The Panorama Patient Monitoring Network is intended for use under the direct supervision of a licensed healthcare practitioner.

Type of Use *(Select one or both, as applicable)*

☑ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Panorama Patient Monitoring Networks provided below.

Device Common Name: Central Station Monitor and Telemetry System

Device Proprietary Name: Panorama Patient Monitoring Network

Submitter:

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Contact:

Yanhong Bai
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Date Prepared: January 8, 2014

Classification Regulation: 21 CFR 870.1025, Class II, Arrhythmia detector and alarm (including ST-segment measurement and alarm)

Panel: Cardiovascular

Classification Regulation, Classification Name and Product Codes:

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
Primary				
MHX	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, physiological, patient (with arrhythmia detection or alarms)
Secondary				

Product Code	Regulation Number	Panel	Regulation Description	Device Common Name
DSI	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	detector and alarm, arrhythmia
MLD	21 CFR 870.1025	Cardiovascular	Arrhythmia detector and alarm (including ST-segment measurement and alarm)	monitor, st segment with alarm
DRT	21 CFR 870.2300	Cardiovascular	Cardiac Monitor (including cardiotachometer and rate alarm)	monitor, cardiac (incl. cardiotachometer & rate alarm)
DQA	21 CFR 870.2700	Cardiovascular	Oximeter	Oximeter
DRG	21 CFR 870.2910	Cardiovascular	Radiofrequency physiological signal transmitter and receiver.	transmitters and receivers, physiological signal, radiofrequency
MSX	21 CFR 870.2300	Cardiovascular	Cardiac monitor (including cardiotachometer and rate alarm).	system,network and communication,physiological monitors

Predicate Device: Panorama Patient Monitoring Network (K142601)

Hypervisor central monitoring system(including telemetry monitoring system,tms-6016) (K132036)

Philips ST/AR ST and Arrhythmia software (K101521)

Indications for Use:

The indications for use for the Panorama Patient Monitoring Network include:

- Viewing real time patient clinical and demographic data
- Graphical and numeric trending of clinical data
- Storing and printing of clinical and demographic data
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The Panorama Patient Monitoring Network is intended for use in a fixed location, in the healthcare facility setting, as a central viewing station. The Panorama Patient Monitoring Network is not intended to be directly connected to the patient at any time or installed in a patient's vicinity.

The Panorama Network includes the Panorama Telemetry System which acquires and monitors physiological data for ambulating patients within a defined coverage area. The system processes the physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations. The Panorama Telemetry System is intended for installation in a hospital or clinical environment to provide clinicians with patient physiological data, while allowing for patient mobility.

The physiological parameters monitored through telemetry include ECG (Lethal and Non-Lethal Arrhythmia Detection, ST Segment Analysis, QT Analysis and heart rate(HR)), blood oxygenation (SpO2), Pulse Rate (PR). Received data is calculated at the Panorama Central Station, and can be displayed, trended, stored and printed at the Panorama Central Station.

The Panorama Patient Monitoring Network is intended for use under the direct supervision of a licensed healthcare practitioner.

Device Description:

The subject Panorama Patient Monitoring Network includes eight Components:

- Panorama Central Station
- Panorama Telemetry System
- Panorama Telepack
- Compatible Physiological Monitor(s)
- ViewStation
- WorkStation
- Web Viewer
- Gateway

1、The **Panorama Central Station** is a device that monitors patients, collects and stores data,and performs alarm notification .The clinical data displayed at the Central Station is derived from compatible physiological monitor(s) or the Panorama Telepack.

2、The **Panorama Telemetry System** is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area.

3、The **Panorama Telepack** is a battery powered ambulatory monitoring device intended for use in a hospital/clinical environment to provide clinicians with patient

physiological data, while allowing for patient mobility. Data received from the Telepack is transmitted to the Panorama Telemetry System .

4、Mindray's cleared **Compatible Physiological Monitors** that transmit patient data to the Central Station include：

- Passport 12M/17M Monitor(K143195)
- Passport 8/12 Monitor(K132662)
- T1(K143195)
- Passport V Monitor(K091834)
- V Series Monitor(K132026)
- DPM 6/7 Monitor(K092449)
- Spectrum/ Spectrum OR Bedside Monitor(K062098)
- Passport 2 Bedside Monitor (K020550)

5、The Panorama **ViewStation** is a software application that allows the user to remotely display and print patient information from the Central Station.

6、The Panorama **WorkStation** is a software application that allows the user to remotely display and print patient information, enter or change patient demographic information, change alarm limits and responses, place patients in standby or discharge patients.

7、The Panorama **Web Viewer** is a software application that provides the user to remotely view patient information from the Central Station through a facilities intranet using a Microsoft Internet Explorer web browser.

8、The Panorama **Gateway** is an embedded Windows XP software application that allows translation of the Mindray proprietary network format into standard formats such as HL7.

Summary of performance testing

- The Panorama Network has been tested and found to be in compliance with recognized safety, performance and electromagnetic compatibility standards.
- A risk analysis has been developed to identify potential hazards and document the mitigation of the hazards. The device's software has been verified and validated in accordance with the appropriate test requirements.
- The Panorama Network has been tested and complies with the following recognized consensus standards:

- ANSI/AAMI ES60601-1
- IEC60601-1-2
- IEC60601-1-6
- IEC60601-1-8
- IEC60601-2-27
- EC57

- ISO80601-2-61

- The Panorama Network was tested and complies with established parameter performance specifications.

- No clinical tests were performed on the Panorama Network. The clinical safety and effectiveness of the central monitoring networks has been long established through analysis of end-user experience and feedback gained through post-market analysis.

Substantial Equivalence:

Comparison of Indications –

The **Panorama Patient Monitoring Network/K142601** shall serve as the primary predicate device respecting Indications for Use, performance specifications and technology.

The **Hypervisor Central Monitoring System /K132036** is provided as a predicate device supporting bispectral index (BIS) that has been added to the subject Panorama. Section 12.4.4 includes additional details related to this new parameter.

The **Philips ST/AR ST and Arrhythmia software/K101521** is provided as a predicate device supporting QT analysis that has been added to the subject Panorama. Section 12.4.1 includes additional details related to this new parameter.

The subject Panorama considered substantially equivalent to the predicate devices respecting the indications for use.

Comparison of Technological Characteristics –

The table below compares the key technological feature of the subject devices to the primary predicate device。

Technology	Subject / Panorama Patient Monitoring Network	Predicate / Panorama Patient Monitoring Network (K142601)
Central Station Telemetry Server Keyboard Mouse Display Operating System Longview-VGA extender	2U (Horizontal) or Vertical 2U (Horizontal) Tower Yes Yes Touch screen Windows XP (embedded) Yes	2U (Horizontal) or Vertical 2U (Horizontal) Tower Yes Yes Touch screen Windows XP (embedded) Yes
Telemetry System TIM Transceiver Frequency Repeater	2U (horizontal rack mount) 4U (horizontal rack mount) WMTS Yes	2U (horizontal rack mount) 4U (horizontal rack mount) WMTS Yes

Antenna	Radio Frequency	Radio Frequency
Telepack	Telepack-608(WMTS)	Telepack-608(WMTS)
Compatible Physiological Monitors	Passport 12M/17M Monitor(K143195) Passport 8/12 Monitor(K132662) T1(K143195) Passport V Monitor(K091834) V Series Monitor(K132026) DPM 6/7 Monitor(K092449) Spectrum/ Spectrum OR Bedside Monitor(K062098) Passport 2 Bedside Monitor (K020550)	Passport 12M/17M Monitor(K143195) Passport 8/12 Monitor(K132662) T1(K143195) Passport V Monitor(K091834) V Series Monitor(K132026) DPM 6/7 Monitor(K092449) Spectrum/ Spectrum OR Bedside Monitor(K062098) Passport 2 Bedside Monitor (K020550)
ViewStation	Yes	Yes
WorkStation	Yes	Yes
Web Viewer	Yes	Yes
Gateway	Yes	Yes
Monitoring Parameters	ECG (Lethal and Non-Lethal Arrhythmia Detection, ST Segment Analysis, QT Analysis and heart rate(HR)), Invasive Blood Pressure (IBP), Non-Invasive Blood Pressure(NIBP), Blood Oxygenation (SpO2), Pulse Rate (PR), Respiration Rate (RESP), Respiration Gases(O2,CO2), Temperature(TEMP), Anesthetic Gases(AG), Cardiac Output(C.O.), Bispectral Index (BIS), and Hemodynamics.	ECG (Lethal and Non-Lethal Arrhythmia Detection, ST Segment Analysis, and heart rate(HR)), Invasive Blood Pressure (IBP), Non-Invasive Blood Pressure(NIBP), Blood Oxygenation (SpO2), Pulse Rate (PR), Respiration Rate (RESP), Respiration Gases(O2,CO2), Temperature(TEMP), Anesthetic Gases(AG), Cardiac Output(C.O.), and Hemodynamics.